



WILLIAM P. DENI, JR.  
Director

Gibbons P.C.  
One Gateway Center  
Newark, New Jersey 07102  
Direct: (973) 596-4853 Fax: (973) 639-8373  
wdeni@gibbonslaw.com

April 10, 2025

**VIA ECF**

Honorable Tonianne J. Bongiovanni, U.S.M.J.  
United States District Court  
District of New Jersey  
Clarkson S. Fisher Building & U.S. Courthouse  
402 East State Street  
Trenton, New Jersey 08608

**Re: *Arbutus Pharma Corp., et al. v. Pfizer Inc., et al.***  
**Civil Action No. 23-1876 (ZNQ) (TJB)**

Dear Judge Bongiovanni:

This firm represents Defendant BioNTech SE in the above-referenced action. We write on behalf of Defendants BioNTech SE and Pfizer Inc. regarding discovery relating to violations of the Stipulated Discovery Confidentiality Order (“DCO”) by Plaintiffs Arbutus Pharma Corp. and Genevant Sciences GmbH. The DCO precludes individuals “involved in strategic business decisions . . . relating to or relevant to RNA vaccines or lipid nanoparticles” from receiving Highly Confidential Information. ECF No. 54 at ¶ 1.4. Yet, Plaintiffs have provided such access to Lindsay Androski, who recently was appointed Arbutus’ Chief Executive Officer—i.e., its most senior strategic business decisionmaker. Arbutus also appointed Ms. Androski to its board of directors.

Defendants respectfully request that the Court immediately enter an order (1) temporarily revoking Ms. Androski’s designation as Designated In-House Counsel under the DCO pending resolution of any DCO violations; and (2) outlining a schedule for Defendants to investigate and address any such violations, including (a) by deposing Ms. Androski as to her access to Confidential and Highly Confidential information and role as Arbutus’ CEO and member of Arbutus’ board of directors, and (b) by seeking further relief from the Court, if appropriate.

**I. Background**

This is a patent litigation concerning Plaintiffs’ allegation that Defendants’ COVID-19 vaccine (Comirnaty®) infringes five asserted patents. ECF No. 1 at ¶¶ 8-9. According to Plaintiffs, Genevant “licenses these patents from Arbutus” and “has several ongoing LNP [(lipid nanoparticle)] product development collaborations, some directed to COVID-19 and some directed to other diseases and disorders.” *Id.* at ¶¶ 1, 39. In addition to its license with Genevant, Plaintiffs contend “Arbutus has licensed its LNP technology to other companies.” *Id.* at ¶ 39. Plaintiffs allege that Defendants’ “COVID-19 mRNA-LNP vaccine products” infringe the patents owned by Arbutus and licensed to Genevant. *Id.* at ¶¶ 8-9.

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Early in this case, the parties agreed to the DCO (ECF No. 54), which allows each party to designate a limited number of in-house counsel as “Designated In-House Counsel.” The DCO provides that Designated In-House Counsel who have access to Highly Confidential Materials<sup>1</sup> “shall not be involved in strategic business decisions (including marketing, financial, product development/design, and pricing decisions, on issues affecting competition) relating to or relevant to RNA vaccines or lipid nanoparticles, including the manufacture or use thereof (‘Strategic Business Decisions’).” ECF No. 54 at ¶ 7.3.

Plaintiffs designated Lindsay Androski as Designated In-House Counsel for Genevant on June 18, 2024. On June 25, Defendants objected to Plaintiffs’ designation, requesting Plaintiffs to “describe Ms. Androski’s relationship with Plaintiffs,” among other inquiries.<sup>2</sup> In their July 1 response, Plaintiffs represented that Ms. Androski “does not currently provide intellectual property advice or counseling to any entity other than Genevant, and will not provide such advice of counseling during the course of this litigation.” Plaintiffs also represented that Ms. Androski “does not make Strategic Business Decisions” as defined in the DCO “*for any of the Plaintiffs*” and does not “sit[] on the Board” or hold “any other position.” (Emphasis added.) In view of Plaintiffs’ representations and the protections set forth in the DCO, Defendants consented to Ms. Androski’s designation under the DCO on July 10, 2024.

After Defendants agreed to Ms. Androski’s designation, Defendants produced thousands of Confidential and Highly Confidential documents. These documents included batch and manufacturing records of the accused Comirnaty® vaccine, sensitive competitive intelligence reports outlining Defendants’ analysis of the industry and their competitors, business plans and forecasts, and financial information. As Designated In-House Counsel, Ms. Androski has access to all these materials. While Plaintiffs refuse to confirm which documents she has received, they confirmed she has received Defendants’ Confidential or Highly Confidential information.

In late February 2025, Defendants discovered a press release announcing that Arbutus had named Ms. Androski as CEO and added her as a member of Arbutus’ board of directors, Ex. A, two material changes from Plaintiffs’ representations which were the basis for Defendants allowing Ms. Androski to have confidential access under the DCO.<sup>3</sup> Neither Genevant nor Arbutus informed Defendants of Ms. Androski’s new role. Plaintiffs also did not seek permission to

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<sup>1</sup> Highly Confidential Materials are defined in paragraph 1.8 as “[c]onfidential trade secret, know-how, personnel, financial, or other proprietary information . . . highly likely to cause significant harm to the competitive, commercial, or financial position of the Designating Party . . . [and] [i]nformation that is highly likely to cause to the interests of individuals . . . who are not parties to the litigation.”

<sup>2</sup> To the extent the Court would like Defendants to provide copies of the parties’ email correspondence, Defendants would be happy to do so.

<sup>3</sup> Arbutus and Genevant are both partly owned by Roivant Sciences. ECF Nos. 3, 4. Arbutus owns a significant share of Genevant and has “a non-voting observer seat on Genevant’s Board of Directors.” *See, e.g.*, Ex. B at 14.

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continue to designate Ms. Androski as Designated In-House Counsel in view of these materially changed circumstances.

Upon learning of Ms. Androski's ascension to CEO and member of the board at Arbutus, Defendants have sought to protect their Confidential and Highly Confidential information, but Plaintiffs have provided little assurances. On February 28, 2025, Defendants asked Plaintiffs to immediately revoke Ms. Androski's status as Designated In-House Counsel and her access to Defendants' Confidential and Highly Confidential Materials. But on March 4, Plaintiffs "disagree[d]" that her continued designation was improper and stated that they "therefore maintain Ms. Androski's designation under the DCO." On March 11, Defendants maintained their objection and asked Plaintiffs basic questions about Ms. Androski's role and the scope of Confidential and Highly Confidential information she had received. On March 19, Plaintiffs did not respond to any of Defendants' questions, and instead reiterated their assertion that "Ms. Androski was and remains a proper designee under the Confidentiality Order and is entitled to view both Confidential and Highly Confidential materials." On March 26, Defendants again emphasized their disagreement and reiterated that, "[u]ntil this issue is resolved, no [Confidential or Highly Confidential] information should be sent to Ms. Androski." The parties met and conferred on April 4, at which point Defendants learned that Plaintiffs would not agree to stop sending Ms. Androski Defendants' Confidential and Highly Confidential information. On April 8, Plaintiffs answered some of Defendants' outstanding questions, but continued to disagree that Ms. Androski was improperly designated and refused to identify what Confidential and Highly Confidential material she had received. Unable to resolve this issue, Defendants now seek relief from the Court.

**II. The Court should immediately revoke Ms. Androski's designation under the DCO while Defendants investigate the extent of DCO violations.**

Pending Defendants' investigation of DCO violations, Defendants respectfully request that the Court immediately revoke Ms. Androski's designation under the DCO, at least temporarily, and require her to return and/or destroy any files or copies of Defendants' Confidential and Highly Confidential information in her possession while this dispute remains pending. Defendants never agreed that their Confidential and Highly Confidential information could be shared with Arbutus' CEO; yet, Plaintiffs nonetheless provided such access. That alone should be sufficient for the Court to at least temporarily revoke Ms. Androski's access to Defendants' Confidential and Highly Confidential information. The Court also should at least temporarily revoke Ms. Androski's designation under the DCO due to high risk that, as Arbutus' top decisionmaker, it is highly likely that Ms. Androski will misuse Defendants' Confidential and Highly Confidential information (even if inadvertently) when making business decisions concerning RNA or lipid nanoparticles, causing Defendants significant harm. Through a deposition of Ms. Androski, Defendants intend to uncover the extent of any current and/or future DCO violations, at which point Defendants will, as appropriate, seek to make her removal from the DCO permanent and additional remedies.

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**A. Caselaw supports revoking Ms. Androski's designation under the DCO due to her role as strategic decisionmaker.**

Courts in the Third Circuit have conducted a two-step analysis to determine whether in-house counsel should have access to an opposing party's confidential and highly confidential materials. *See Sanofi-Aventis U.S. LLC v. Breckenridge Pharm., Inc.*, 2016 WL 308795 at \*3 (D.N.J. Jan. 25, 2016) (citing *U.S. Steel Corp. v. United States*, 730 F.2d 1465 (Fed Cir. 1984)). First, courts are to assess "[w]hether an unacceptable opportunity for inadvertent disclosure exists," which can be present "where in-house counsel are involved in competitive decisionmaking." 730 F.2d at 1469. Competitive decisionmaking may include "counsel's activities, association, and relationship with a client that are such as to involve counsel's advice and participation in any or all of the client's decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor." *Id.* at 1468, n.3. Second, a court "must balance [risk of disclosure] against the potential harm to the opposing party from restrictions imposed on that party's right to have the benefit of counsel of its choice." *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1380 (Fed. Cir. 2010) (citing *U.S. Steel*, 730 F.3d at 1468).

Here, Ms. Androski is not simply opposing counsel "involved in competitive decisionmaking with its client"—she *is* the client's top employee. *Deutsche Bank*, 605 F.3d at 1378. Ms. Androski is the CEO of a company that, in Plaintiffs' own words, is engaged in the business of "licens[ing] its LNP technology" to Genevant, Alnylam, and "other companies." ECF No. 1 at ¶ 39. Plaintiffs have also alleged in this case that "Genevant's mission is to utilize its LNP and other technologies to deliver innovative new medicines that use mRNA or other nucleic acids," *id.* at ¶ 11, and Arbutus is a part-owner of Genevant and has "a non-voting observer seat" on its board of directors, Ex. B at 14. Ms. Androski's self-described goals of "advancing [Arbutus'] pipeline" and "maximizing the company's contributions to LNP delivery technology through Genevant" strongly suggest that she is involved in Arbutus' LNP-related business decisions. Ex. A. Such activities conflict with the DCO's express bar on being "involved in strategic business decisions . . . relating to or relevant to RNA vaccines or lipid nanoparticles." ECF No. 54 at ¶ 1.4.

Plaintiffs have emphasized that Arbutus is focused on developing a *non*-LNP treatment for HBV, but in addition to Arbutus' LNP-based business arrangements with other companies, Arbutus has made clear that LNPs are "relevant" to its HBV products. *See* ECF No. 54 at ¶ 1.4. Its former CEO announced that Arbutus "has established a dominant position in LNP technology including key patents, knowhow and manufacturing trade secrets which we are applying to our HBV franchise." Ex. C. And Arbutus' website also touts that "Arbutus retained all rights to its LNP and conjugate delivery platforms for HBV." Ex. D.

Particularly in the context of the temporary revocation that Defendants currently seek, the risk of disclosure of Defendants' Highly Confidential Information outweighs any harm to Plaintiffs from not having Ms. Androski Designated-In-House Counsel. *See, e.g., Vivus, Inc.*, 2016 WL 590212 at \*3-4 (D.N.J. Feb. 16, 2016) (restricting counsel's access even though she was one of

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only two counsel employed at company and represented that she was “the only attorney ... capable of performing [her] duties”). Plaintiffs have other Designated In-House Counsel in this litigation, including Genevant’s Chief Legal Officer, Pete Zorn. Upon information and belief, Plaintiffs also employ other legal counsel within their in-house legal departments. There is no reason to believe that Mr. Zorn alone or together with other in-house counsel who are not competitive decision-makers employed by Plaintiffs are incapable of representing Plaintiffs in this matter, and Plaintiffs have not articulated why limiting their counsel to these individuals would be insufficient. In view of the highly-sensitive material produced in this litigation—including Defendants’ sensitive business plans, analysis of competitors, future products using LNP delivery technology, and financial information—the stakes are too high to permit Arbutus’ CEO to have continued access.

**B. The Court should maintain Ms. Androski’s revocation until Defendants have had an opportunity to depose her and seek additional remedies, as appropriate.**

Defendants request that the Court preclude Ms. Androski from receiving or maintaining Defendants’ Confidential and Highly Confidential information until Defendants (1) have had an opportunity to depose Ms. Androski, and (2) have obtained resolution of any further remedies in connection with Plaintiffs’ DCO violations.

At this stage, Defendants have been unable to obtain necessary information from Plaintiffs regarding Ms. Androski’s responsibilities at Arbutus or her access to Defendants’ protected materials. Because Plaintiffs have refused to disclose what sensitive documents Ms. Androski has accessed, Defendants do not know specifically how her access to such information may harm Defendants in view of her responsibilities at Arbutus and connection with Genevant. Ms. Androski is uniquely positioned to know what her job entails as Arbutus’ CEO, what specific information she has accessed from Defendants, and how she has used any such information. Plaintiffs have thus created a situation where a deposition of Ms. Androski is now the only reasonable means for Defendants to learn the full extent of any DCO violation, including what relief is necessary to remedy any such violations.

Defendants anticipate that, following Ms. Androski’s deposition and the completion of their investigation, Defendants may seek additional relief from the Court, including but not limited to permanent revocation of her ability to access Defendants’ confidential DCO information. Defendants respectfully request that the Court enter a scheduling order to allow for such briefing following Defendants’ deposition of Ms. Androski and maintain Ms. Androski’s revocation until any such briefing is resolved.

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We thank the Court for its attention to this matter and are available at the Court’s convenience to address any questions or concerns.

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Respectfully submitted,

s/ William P. Deni, Jr.  
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cc: All counsel of record (via ECF)